

assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2314, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 872.1500 Gingival fluid measurer.

(a) *Identification.* A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38797, July 25, 2001]

§ 872.1720 Pulp tester.

(a) *Identification.* A pulp tester is an AC or battery powered device intended to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.

(b) *Classification.* Class II.

§ 872.1730 Electrode gel for pulp testers.

(a) *Identification.* An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989; 66 FR 38797, July 25, 2001]

§ 872.1740 Caries detection device.

(a) *Identification.* The caries detection device is a device intended to show the existence of decay in a patient's tooth by use of electrical current.

(b) *Classification.* Class II.

§ 872.1745 Laser fluorescence caries detection device.

(a) *Identification.* A laser fluorescence caries detection device is a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.

(b) *Classification.* Class II, subject to the following special controls:

(1) Sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter;

(2) Premarket notifications must include clinical studies, or other relevant information, that demonstrates that the device aids in the detection of tooth decay by measuring increased laser induced fluorescence; and

(3) The labeling must include detailed use instructions with precautions that urge users to:

(i) Read and understand all directions before using the device,

(ii) Store probe tips under proper conditions,

(iii) Properly sterilize the emitter-detector handpick before each use, and

(iv) Properly maintain and handle the instrument in the specified manner and condition.

[65 FR 18235, Apr. 7, 2000]

§ 872.1800 Extraoral source x-ray system.

(a) *Identification.* An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification.* Class II.

§ 872.1810 Intraoral source x-ray system.

(a) *Identification.* An intraoral source x-ray system is an electrically powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the

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teeth, jaw, and oral structures. The x-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification*. Class II.

§ 872.1820 Dental x-ray exposure alignment device.

(a) *Identification*. A dental x-ray exposure alignment device is a device intended to position x-ray film and to align the examination site with the x-ray beam.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38797, July 25, 2001]

§ 872.1830 Cephalometer.

(a) *Identification*. A cephalometer is a device used in dentistry during x-ray procedures. The device is intended to place and to hold a patient's head in a standard position during dental x-rays.

(b) *Classification*. Class II.

§ 872.1840 Dental x-ray position indicating device.

(a) *Identification*. A dental x-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the x-ray beam and to restrict the dimensions of the dental x-ray field by limiting the size of the primary x-ray beam.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38797, July 25, 2001]

§ 872.1850 Lead-lined position indicator.

(a) *Identification*. A lead-lined position indicator is a cone-shaped device lined with lead that is attached to a dental x-ray tube and intended to aid in positioning the tube, to prevent the misfocusing of the x-rays by absorbing

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divergent radiation, and to prevent leakage of radiation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38797, July 25, 2001]

§ 872.1870 Sulfide detection device.

(a) *Identification*. A sulfide detection device is a device consisting of an AC-powered control unit, probe handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.

(b) *Classification*. Class II (special controls) prescription use in accordance with § 801.109 of this chapter; conformance with recognized standards of biocompatibility, electrical safety, and sterility; clinical and analytical performance testing, and proper labeling.

[63 FR 59717, Nov. 5, 1998]

§ 872.1905 Dental x-ray film holder.

(a) *Identification*. A dental x-ray film holder is a device intended to position and to hold x-ray film inside the mouth.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989; 66 FR 38797, July 25, 2001]